GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4755
ANSWERED ON:18.04.2001
ILL AFFECTS OF CONTAMINATED TRANSFUSION OF FLUID
RAMSHETH THAKUR

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware that contaminated transfusion of fluids are administered in many Government hospitals resulting in death of patients;

(b) if so, the number of such cases noticed by the Government during the last two years, till date;

(c) whether an expert committee of the National Human Rights Commission had made certain recommendations for ensuring quality health care products to patients after contaminated bottles of LVP were detected in Ram Manohar Lohia Hospital;

(d) if so, details of the said recommendations; and

(e) the reasons for not executing the same by the all Government hospitals?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) There is no such report during the last two years.

(c) to (e) Yes, Sir. The details of recommendations are as under:-

1. Develop policies and procedures for the procurement of medicines and inventory control, receipt, handling, storage, quality control, distribution and dispensing etc.

2. Develop policies and procedures for handling of quality related complaints, all medication errors and adverse drug reactions (ADRs).

3. Develop good hospital warehousing practices including rodent control an frame good warehousing practice guidelines. It shall impart training to hospital staff in Good Warehousing Practices and ensure maintenance of records of defective stocks, at one place. It shall prepare guidelines and ensure safe custody of defective samples drawn by Regulatory Authorities.

4. Impart continuing education to hospital staff, including pharmacists, nurses, doctors in the visual inspection of particulate matter before administering I.V. fluids to patients.

5. Develop flow chart for complaint handling procedure and for partnership for networking within manufacturers and Regulatory Agencies for speedy disposal of defective and recalled goods.

6. Prepare guidelines on sampling of stocks including complaint samples, by approved testing laboratories detailing exact quantity to be drawn, fixing responsibility for drawing samples.

National Human Rights Commission had also made recommendation concerning review of Schedule M to the Drugs & Cosmetics Rules, 1945 for up-gradation of Good Manufacturing Practices (GMPs) for manufacture,storage, distribution, warehousing of I.V. Fluids.
In this regard, Government has initiated steps to upgrade the requirement under the existing Schedule M in terms of requirement of premises, plant, equipments and areas for pharmaceutical products. The draft upgraded Schedule M, vide draft notification No.GSR 8(E) dated 4.1.2001, now includes a separate part having specific requirements on strict control of manufacture of LVPs both in glass and plastics containers, in terms of building & civil work, air handling system (central air conditioning), environment monitoring, sanitation, equipments, water systems, manufacturing & sterilization processes, documentation, areas needed etc

The Government has circulated the draft notification to the manufactures to elicit their views before finalizing the proposal and amendments to Schedule M under the Drugs & Cosmetics Rules, 1945.